Association for the Advancement of Blood & Biotherapies

AABB Information Technology in Blood Banking and Transfusion Services Training Modules & Certificate Program

References

Purpose: this resource is being provided by AABB to use for future reference after you complete this educational module. AABB will periodically review this document for accuracy. Please submit any broken links to eLearning@aabb.org (please include a subject line of AABB IT Certificate Reference Document).

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Module 3
Regulating and Accrediting Authorities in Blood Banking

AABB
www.aabb.org

The American Society for Histocompatibility and Immunogenetics (ASHI)
https://www.ashi-hla.org/

Centers for Medicare & Medicaid Services (CMS) / Clinical Laboratory Improvement Amendments (CLIA)
https://www.cms.gov / https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index

College of American Pathologists (CAP)
https://www.cap.org/

Foundation for the Accreditation of Cellular Therapies (FACT)
http://www.factwebsite.org/

The Joint Commission
https://www.jointcommission.org/

U.S. Department of Health & Human Services

- https://www.hhs.gov/hipaa/index.html
- HHS/Health Information Privacy/HIPAA Enforcement: https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/index.html

U.S. Food & Drug Administration (FDA)

Blood Establishment Computer System Validation in the User's Facility
https://www.fda.gov/media/72533/download

Blood Establishment Registration and Product Listing
https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing

Center for Biologics Evaluation and Research (CBER)
https://www.fda.gov/about-fda/about-center-biologics-evaluation-and-research-cber/about-cber

Center for Drug Evaluation and Research
https://www.fda.gov/about-fda/office-medical-products-and-tobacco/center-drug-evaluation-and-research-cder

Center for Devices and Radiological Health
https://www.fda.gov/about-fda/office-medical-products-and-tobacco/about-center-devices-and-radiological-health

eCFR – Electronic Code of Federal Regulations Title 21

- 21 eCFR Part 80: ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES
  https://www.ecfr.gov/cgi-bin/text-idx?SID=ae155e4f81721d356edf17f302890a27&mc=true&node=pt21.8.807&rgn=div5
- 21 CFR 820: Quality System Regulation
  https://www.ecfr.gov/cgi-bin/text-idx?SID=c1dee1c87f293d048b2f2c25899e3f48&mc=true&tpl=/ecfrbrowse/Title21/21cfr820_main_02.tpl

FDA CLIA Categorizations
https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-categorizations

FDA/Regulatory Information/About FDA Guidance
https://www.fda.gov/regulatory-information/search-fda-guidance-documents

FDA/Medical Devices/Cybersecurity
https://www.fda.gov/medical-devices/digital-health/cybersecurity

FDA/Blood & Blood Products
https://www.fda.gov/vaccines-blood-biologics/blood-blood-products

FDA Education and Resources by Subject
https://www.fda.gov/training-and-continuing-education/fda-learning-portal-students-academia-and-industry/fda-education-and-resources-subject#biologics

Federal Food, Drug, and Cosmetic Act (FD&C Act)/Regulation Information
https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act

Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors
https://www.fda.gov/media/84887/download

Postmarket Management of Cybersecurity in Medical Devices

https://www.fda.gov/media/95862/download

Quality System (QS) Regulation/Medical Device Good Manufacturing Practices
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm

UDI Benefits
https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/benefits-udi-system

Nuclear Regulatory Commission
https://www.nrc.gov/